Effective	Revised labeling due	Drug class	Mail routing code
Do	.....do	Antithyroids	Do.
Do	.....do	Polymyxins	HFD–520.
Do	.....do	Antineoplastics	HFD–150.
Mar. 1, 1984	Mar. 1, 1982	Urinary tract stimulants	HFD–110.
Do	.....do	Urinary tract relaxants	Do.
Do	.....do	Antimigraine	HFD–120.
Do	.....do	Adjuncts to anethesia	HFD–160.
Apr. 1, 1984	Apr. 1, 1982	Antianginals	HFD–110.
Do	.....do	Laxatives	Do.
Do	.....do	CNS stimulants	HFD–120.
Do	.....do	Anorexiants	Do.
Do	.....do	Chloramphenicol and derivatives	HFD–520.
May 1, 1984	May 1, 1982	Drugs indicated for vertigo/motion sickness/vomiting	HFD–120.
Do	.....do	Antidiuretics	HFD–510.
Do	.....do	Contraceptives	Do.
Do	.....do	Macrolides	HFD–520.
Do	.....do	Lincosamides	Do.
Do	.....do	Antiarthritics	HFD–150.
Do	.....do	Antitussives	HFD–160.
Do	.....do	Expectorants	Do.
Do	.....do	Inhalants	Do.
June 1, 1984	June 1, 1982	Urinary tract antiseptics	HFD–520.
July 1, 1984	July 1, 1982	Chelating agents/heavy metal antagonists	HFD–110.
Do	.....do	All other gastrointestinal drugs	HFD–110.
Do	.....do	Antianxiety	HFD–120.
Do	.....do	Drugs indicated for myasthenia gravis	HFD–120.
Do	.....do	All other antiinfective drugs	HFD–520.
Do	.....do	Bronchodilators/antiasthmatics	HFD–160.
Aug. 1, 1984	Aug. 1, 1982	Estrogens	HFD–510.
Do	.....do	Uterine stimulants	HFD–510.
Do	.....do	Uterine relaxants	Do.
Sept. 1, 1984	Sept. 1, 1982	Drugs indicated for hypotension and shock	HFD–110.
Oct. 1, 1984	Oct. 1, 1982	All other cardiac drugs	HFD–110.
Do	.....do	Nasal decongestants	HFD–160.
Nov. 1, 1984	Nov. 1, 1982	All other prescription drugs.	

[1] Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).
[2] Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990]

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§ 201.60 Principal display panel.

The term *principal display panel,* as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious ''principal display panel'' such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 201.61 Statement of identity.

(a) The principal display panel of an over-the-counter drug in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s) in terms that are meaningful to the layman. Such statements shall be placed in direct conjunction with the most prominent display of the proprietary name or designation and shall employ terms descriptive of general pharmacological category(ies) or principal intended action(s); for example, ''antacid,'' ''analgesic,'' ''decongestant,'' ''antihistaminic,'' etc. The indications for use shall be included in the directions for use of the drug, as required by section 502(f)(1) of the act and by the regulations in this part.

(c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§ 201.62 Declaration of net quantity of contents.

(a) The label of an over-the-counter drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination or numerical count and weight, measure, or size. The statement of quantity of drugs in tablet, capsule, ampule, or other unit form and the quantity of devices shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of fluid measure if the drug is liquid. The drug quantity statement shall be augmented when necessary to give accurate information as to the strength of such drug in the package; for example, to differentiate between several strengths of the same drug ''100 tablets, 5 grains each'' or ''100 capsules, 125 milligrams each'' or ''100 capsules, 250 milligrams each'': *Provided,* That:

(1) In the case of a firmly established, general consumer usage and trade custom of declaring the quantity of a drug in terms of linear measure or measure of area, such respective term may be used. Such term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire drug; for example, the net quantity of adhesive tape in package form shall be expressed in terms of linear measure augmented by a statement of its width.

(2) Whenever the Commissioner determines for a specific packaged drug that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisons by consumers, he